Hepatitis B

Surveillance Protocol

WEST VIRGINIA Department of Health & Human Resources
BUREAU FOR PUBLIC HEALTH

Provider Responsibilities

1. Report cases of acute, chronic, or perinatal hepatitis B to the local health department within 24 hours of diagnosis
2. Evaluate and test patients who present with signs and symptoms of acute hepatitis
3. Conduct appropriate screening of pregnant females
4. Consider screening patients who are asymptomatic but who have risk factors
5. Receive disease reporting education from local health departments
6. Anticipate the need to work with local health departments to
    a. Supply appropriate clinical information
    b. Supply additional lab results

Laboratory Responsibilities

1. For paper copies of positive laboratory results for hepatitis B (HBsAg, anti-HBc IgM, HBeAg, HBV DNA) forward a copy to the local health department within 24 hours of report. For electronic lab reporting facilities the positive laboratory results must be reported to the State Health Department within 24 hours of report.
2. Please include:
    a. Patient's full name, date of birth, address and phone number.
    b. Patient's demographic information including age, sex, race, and ethnicity (if available)
    c. Full physician name, address, and phone number
    d. Laboratory results, normal values, and interpretation including:
        i. IgM antibody to HAV (IgM anti-HAV)
        ii. Hepatitis B surface antigen (HBsAg)
        iii. IgM antibody to Hepatitis B core antigen (IgM anti-HBc)
        iv. Antibody to HCV (anti-HCV)
        v. Any additional Hepatitis B screening tests
        vi. Bilirubin
        vii. Transaminase levels

Local Health Responsibilities

1. **Education and Outreach**
    a. Educate providers about the importance and the appropriate use of hepatitis B vaccine, especially in newborns and adolescents.
    b. Educate providers about the importance of identifying pregnant women who are hepatitis B positive and the importance of notifying public health.

West Virginia Bureau for Public Health
Office of Epidemiology and Prevention Services
Division of Infectious Disease Epidemiology
350 Capitol Street, Room 125, Charleston, WV 25301-3715
Phone: 304.558.5358 Fax: 304.558.6335 www.dide.wv.gov

c. Educate the general public about hepatitis B risk factors, hepatitis B vaccine, and prevention of hepatitis B transmission.
d. Per the Reportable Disease Rule (WV Code 16-3-1; 64CSR7):
    i. Educate health care provider about the requirement to report hepatitis B, acute, chronic or perinatal to the local health department within 24 hours of diagnosis
    ii. Educate laboratories about the requirement to report hepatitis B surface antigen (HBsAg) positive and/or IgM antibody to hepatitis B core antigen (HBcAb-IgM) labs to the local health department within 24 hours of report.

2. **Investigations** Note: Completion of the WVEDSS Hepatitis Case Report will ensure a complete and appropriate investigation. **http://www.dhhr.wv.gov/oeps/disease/WVEDSS/Documents/Hepatitis%20B%20Acute%20and%20Chronic%20case%20investigation.pdf**
    a. Within 24 hours of receiving a report of a HBsAg, HBeAg or HBV DNA positive patient the local health department will perform the following actions:
        i. Conduct a record search to determine if the patient was previously investigated
        ii. Contact the physician to gather the additional clinical information
            1. Patient's demographic information
            2. Clinical information
            3. **Patient's pregnancy status** (If yes, notify the Perinatal Hepatitis B Coordinator at 1-800-642-3634)
            4. Other related lab results – hepatitis A, hepatitis C, or liver enzymes
            5. History of drug abuse or alcohol abuse
            6. Hepatitis B vaccination history
            7. Determine if the patient is aware of diagnosis
            8. Inform the provider that you will be contacting the patient to complete the public health investigation
        iii. Interview patient to collect the following information:
            1. Any missing clinical information
            2. Exposure and risk factor information
            3. Evaluate for potential health care associated exposure including:

a. No risk factor identified other than a health care procedure that occurred within 180 days of the date of onset of symptoms (See Page 3, Section 4)
4. Hepatitis B vaccination records
5. Information about contacts
    a. Name of contact
    b. Type of contact
    c. How to get in touch with the contact

iv. Public Health Action
1. Provide education on hepatitis B prevention and transmission
2. Refer the patient to a physician for further testing and disease management
3. Notify, and investigate potential contacts of the index case (See page 4, Section 6)
    a. Provide education on hepatitis B prevention and transmission to contacts
    b. Provide testing, vaccine, and post exposure prophylaxis (PEP) (See table 1) and hepatitis B vaccine to contacts at no charge. Note: On the WV OLS lab specimen submission form, patient type is "investigation."

b. Document public health actions taken and date action was taken in the WVEDSS investigation
c. **WVEDSS -**
    i. Complete the case investigation in WVEDSS
    ii. Submit report for regional review

3. The local health department should assure that all patients who are HBsAg, HBeAg, or HBV DNA positive receive education on hepatitis B prevention and transmission.
4. If the patient has had an invasive medical procedure within 180 days prior to the date of onset of symptoms, and reports no other risk factors, local health should report this to the Division of Infectious Disease Epidemiology (DIDE) at (304)558-5358, extension 1 immediately. A suspect case of health care associated hepatitis B infection warrants an investigation. Steps for investigation a single case of hepatitis B infection suspected of being related to health care delivery can be found at: http://www.cdc.gov/hepatitis/outbreaks/pdfs/healthcareinvestigationguide.pdf
5. **Lost to Follow Up/Disease Intervention Specialists**

a. Each health department should maintain a policy on how to manage patients who are lost to follow up.
b. A case may be considered lost to follow up at the local level two weeks after the case was first assigned and after the local health department has documented a "good faith effort" in WVEDSS to contact the patient which includes at least:
    i. Three phone call attempts
    ii. Two letters (preferably one being a certified letter)
c. If the local health department is still unable to locate the patient after two weeks, the case may be submitted to the state for review as "lost to follow up."
d. The Hepatitis B epidemiologist will then submit the case as lost to follow up to the Disease Intervention Specialist Supervisor, who will then assign the case to the appropriate Disease Intervention Specialist.
e. The disease Intervention Specialist will perform the following duties:
    i. Interview the patient for all contacts (sexual, household, drug paraphernalia use)
    ii. Provide partner notification to named contacts
    iii. Complete Interview Record (73.54) and Field Record (2936) as necessary and submit to the DIS Supervisor
    iv. Complete the Hepatitis Case Report and submit to the local health department for completion of the case investigation in WVEDSS
    v. Follow up with cases and contacts as necessary to assure that they receive education, testing, vaccination, and PEP as needed
f. The DIS will attempt to locate the patient for up to 4 weeks after receiving the field record. If they are unable to locate the patient then the patient will be called lost to follow up.

6. **Managing contacts of acute and chronic cases**
    a. Provide partner notification to:
        i. Sexual partners
        ii. Household contacts
        iii. Needle/drug paraphernalia sharing contacts
    b. Complete the contact tracing tab in the WVEDSS investigation
    c. Testing Contacts
        i. Submit a blood sample from the contact(s) to the West Virginia Office of Laboratory Services (OLS) for a hepatitis B screen and enter the results into WVEDSS

d. Vaccinating Contacts
   i. Administer hepatitis B immunoglobulin (HBIG) when appropriate (see Table 1) and the first dose of hepatitis B vaccine to the contact(s).
   ii. If the hepatitis serologies are positive, stop the vaccination series and refer the patient for medical care. If serologies are negative, complete full immunization series.
   iii. If a patient receives HBIG and/or hepatitis B vaccine, the local health department should document vaccines administered into the WVEDSS investigation (Enter hepatitis B vaccination into WVSIIS)
   iv. If the source patient has chronic hepatitis B or develops a chronic infection, all household contacts should receive the hepatitis B vaccine series.

Table 1

	Testing Recommended	Immunization Recommended	HBIG Recommended
Contacts – Hepatitis B Acute Case			
Sexual contact of acute case of hepatitis B within last 14 days	Yes	Yes	Yes
Household contact of acute case, no known blood/body fluid exposure	Yes	Yes	No
Household contacts of acute case, known exposure within last 14 days (e.g. shared toothbrush, razor, blood contact)	Yes	Yes	Yes
Needle sharing contact within last 7 days	Yes	Yes	Yes
Contacts – Hepatitis B Chronic Case			
Sexual contact of chronic case of hepatitis B	Yes	Yes	No
Household contact (any) of chronic case of hepatitis B	Yes	Yes	No
Needle sharing contact	Yes	Yes	No

e. Provide education to contacts about hepatitis B prevention and transmission

f. Document public health actions taken and date action was taken in the WVEDSS investigation

State Health Responsibilities

1. Prompt and complete reporting of hepatitis cases to the Center for Disease Control (CDC) through WVEDSS
2. Report cases of hepatitis B to the CDC within 7 days of notification
3. Provide technical expertise and consultation regarding surveillance, investigation, control measures and prevention of hepatitis B
4. Notify the CDC of suspected outbreaks identified in West Virginia and assist local health jurisdictions in obtaining the knowledge and resources necessary for investigations of a hepatitis B outbreak.
5. Summarize surveillance data for hepatitis B on an annual basis
6. Provide Hepatitis B Immunoglobulin (HBIG) and vaccines for contacts of acute cases to local health departments
7. Offer laboratory testing of hepatitis B through the Office of Laboratory Services (OLS) at no cost for the contacts of acute and chronic HBV cases.
8. Assist with difficult investigations including:
    a. Interface with providers on behalf of local health departments as necessary
    b. Provide assistance via Disease Intervention Specialists to local health departments for investigating cases that are lost to follow up
    c. Investigation of possible exposures in unusual settings
    d. Investigation of health care associated hepatitis B infections

Disease Control Objectives

1. Identify and investigate community-based and health care associated outbreaks of hepatitis B in a timely fashion so that appropriate control measures can be applied.
2. Reduce transmission from persons with hepatitis B infection including:
    a. Perinatal transmission; and
    b. Transmission to household, sexual, and drug-using partners.

Disease Prevention Objectives

1. Reduce the incidence of hepatitis B by:
    a. Assuring full hepatitis B immunization of all infants.
    b. Assuring “catch-up” hepatitis B immunization of all adolescents at the adolescent visit**.**

c. Assuring full hepatitis B immunization of high-risk individuals to include:
    i. Sexually active adolescents and adults (including adolescents in STD clinics)
    ii. Household contacts and sexual partners of HBV carriers
    iii. Health care personnel and those who have occupational exposure to blood
    iv. Residents and staff of institutions for the developmentally disabled
    v. Hemodialysis patients
    vi. Recipients of certain blood products
    vii. International travelers
    viii. Injection drug users and
    ix. Inmates in long term correctional facilities
d. Reduce the incidence of hepatitis B through community education and programs to prevent drug use and sharing of needles.
e. Prevent nosocomial transmission of hepatitis B through effective infection control measures.
f. Prevent transmission of hepatitis B through screening of blood and organ donors.
g. Prevent perinatal transmission of hepatitis B by screening pregnant women and administering HBIG and hepatitis B vaccine to babies born to HBsAg positive mothers, within 12 hours of delivery.

Disease Surveillance Objectives

1. Determine the incidence of acute hepatitis B in West Virginia.
2. Determine the risk factors associated with acute hepatitis B in West Virginia.
3. Determine the demographic characteristics of persons with acute and chronic hepatitis B.
4. Distinguish between failure to immunize (preventable cases) versus failure of vaccine (non-preventable cases) among the reason(s) for continued occurrence of hepatitis B.
5. Detect outbreaks, clusters, or unusual patterns of transmission of hepatitis B.
6. Estimate the annual number of newly diagnosed chronic cases of hepatitis B.

Public Health Significance

Hepatitis B is a vaccine preventable disease. When the vaccine was first introduced in 1982, it was recommended for high-risk groups (e.g. men who have sex with men, persons with multiple sexual partners or a history of a sexually transmitted disease, injection drug users, health care workers or persons with occupational exposure to blood, etc.). However, the number of cases of hepatitis B continued to increase after the vaccine was introduced. In 1991, universal infant immunization was instituted, followed by a recommendation for catch-up

vaccination of adolescents in 1996. At this time, the incidence of hepatitis B is declining in the U.S.

Chronic hepatitis B virus infection is associated with the development of hepatocellular carcinoma. According to the CDC, one of 20 persons in the U.S. has been infected with hepatitis B virus during their lifetime (about 12.5 million); one of 200 persons has chronic (lifelong) infection with hepatitis B virus (about 1.25 million); and 4,000 to 5,000 persons die each year from hepatitis B-related chronic liver disease (cirrhosis, liver cancer).

In the United States, children become infected with HBV through a variety of means. The risk of perinatal HBV infection among infants born to HBV-infected mothers ranges from 10% to 85% depending on each mother's hepatitis B *e* antigen (HBeAg) status. Infants who become infected by perinatal transmission have a 90% risk of chronic infection, and up to 25% will die of chronic liver disease as adults. Even when not infected during the perinatal period, children of HBV-infected mothers remain at high risk of acquiring chronic HBV infection by person-to-person horizontal transmission during the first five years of life. More than 90% of these infections can be prevented if HBsAg positive mothers are identified so that their infants can receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) soon after birth.

Significance of Health Care Associated Infections

Health care exposures should be considered when investigating a case of acute hepatitis B infection that has no other risk factors than a health care procedure that occurred within 180 days prior to the date of onset of symptoms. Any single case of suspected health care associated hepatitis B infection warrants an investigation. Investigation of these suspected cases is a vital public health response, as it can result in the identification of an outbreak and/or unsafe clinical practices that can place additional patients at risk. Steps for investigating a single case of hepatitis B infection suspected of being related to health care delivery can be found at: http://www.cdc.gov/hepatitis/outbreaks/pdfs/healthcareinvestigationguide.pdf

Clinical Description

Signs and Symptoms of Acute Disease

People acutely infected with hepatitis B virus may be asymptomatic or symptomatic. Typical symptoms include tiredness, headache, loss of appetite, nausea, vomiting, fever, and chills

with onset three to 10 days prior to jaundice. Right upper quadrant pain is common. Urine may become dark, and stools may become clay-colored. The hallmark of the disease is jaundice (yellow color of the skin and sclera). Infants and children are usually asymptomatic, and an estimated 50% of adults with acute HBV are asymptomatic.
Fulminant hepatitis occurs in very few patients and is usually fatal. Duration of illness is usually several weeks, with symptoms occasionally persisting beyond three to four months.

Signs and Symptoms of Chronic Infection
Ninety to ninety-four percent of adults with acute HBV will develop protective antibodies within six months of the infection. A small proportion (6-10%) of adult patients with acute HBV will develop chronic infection. Most persons with chronic infection will not have symptoms but will continue to be infectious. Complications of chronic hepatitis B infection may include cirrhosis and hepatocellular carcinoma.

Etiologic Agent
HBV is a small double-stranded DNA virus. The outer protein coat contains the hepatitis B surface antigen.

Reservoir
Humans are the only known host.

Mode of Transmission
The virus is transmitted by parenteral or mucosal exposure to HBsAg positive bodily fluids from an infected person. The virus can be found in blood, body fluids (e.g. wound exudates), semen, cervical fluid, and saliva of persons who are HBsAg positive. Blood and serous fluids have the highest concentration of virus, and saliva the lowest. There appears to be no transmission of HBV via tears, sweat, urine, stool, or droplet nuclei.

In the United States, the most common risk factor for transmission of HBV is sexual contact with an infected person; however, the greatest risk for development of chronic infection is through perinatal transmission**.** Perinatal transmission from mother to infant at birth is very efficient. Transmission of perinatal HBV infection can be prevented in approximately 95% of

infants born to HBsAg-positive mothers when immunization and HBIG is administered to the infant within 12 hours of birth.

Person-to-person transmission of HBV can occur in settings involving interpersonal contact over extended periods of time, such as in a household with a person with chronic HBV infection. Transmission from sharing inanimate objects may also occur because HBV can survive at room temperature for up to seven days but is inactivated by commonly used disinfectants, such as a 1:10 bleach solution. HBV is not transmitted by the fecal oral route.

Incubation Period

The incubation period is usually 45 to 180 days, with an average of 60 to 90 days. Time to detection of HBsAg can be as short as two weeks or as long as six months, depending on inoculum, host factors, and other variables.

Period of Communicability

All persons who are HBsAg positive are potentially infectious. The presence of HBeAg is associated with a very high level of infectivity.

Outbreak Recognition

Outbreak-associated HBV and HCV infections are defined as those with epidemiologic evidence supporting health care related transmission and include patients/residents identified with acute infection, or previously undiagnosed chronic infections with epidemiologic evidence indicating that these were likely outbreak-related incident cases that progressed from acute to chronic. Patients/residents identified as likely (previously infected) sources for transmission are not included. In the outbreak investigation setting case definitions are based on laboratory profile and clinical evidence rather than CDC surveillance case definitions which may omit asymptomatic cases.

Acute HBV is typically defined as having a positive hepatitis B surface antigen and positive IgM core antibody, or positive surface antigen and negative total core antibody (early infection). Chronic HBV is typically defined as having a positive hepatitis B surface antigen, positive total core antibody and negative IgM core antibody.

Hepatitis B

Surveillance Protocol

Case Definitions

Hepatitis B, Acute (2012 Case Definition)

Clinical Description

An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >100 IU/L.

*A documented negative hepatitis B surface antigen (HBsAg) laboratory test result within 6 months prior to a positive test (either HBsAg, hepatitis B "e" antigen (HBeAg), or hepatitis B virus nucleic acid testing (HBV NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.

Laboratory Criteria for Diagnosis

HBsAg positive, AND Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done) IgM anti-HAV negative (if done).

Case Classification

Confirmed - A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis B.

Not a case – Any case that does not meet ALL of the requirements listed above for a confirmed case.

Hepatitis B, Chronic (2012 Case Definition)

Clinical Description

No symptoms are required. Persons with chronic hepatitis B virus (HBV) infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

Laboratory Criteria for Diagnosis

Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing), OR

West Virginia Bureau for Public Health
Office of Epidemiology and Prevention Services
Division of Infectious Disease Epidemiology
350 Capitol Street, Room 125, Charleston, WV 25301-3715
Phone: 304.558.5358 Fax: 304.558.6335 www.dide.wv.gov

Hepatitis B

Surveillance Protocol

HBsAg positive or nucleic acid test for HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable)

Case Classification

Probable - A person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

Confirmed - A person who meets either of the above laboratory criteria for diagnosis.

Comment(s)

Multiple laboratory tests indicative of chronic HBV infection may be performed simultaneously on the same patient specimen as part of a "hepatitis panel." Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative AND HBV DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.

Preventive Interventions

Hepatitis B vaccine is a very safe and effective vaccine for prevention of hepatitis B, and it is recommended for all babies, for adolescents who have not already had the vaccine, and for people who are at risk for hepatitis B:

1. Babies who are born to a mother who is HBsAg positive
2. People who have a job that involves contact with blood and blood products
3. Injection drug users
4. Sexually active persons who have had more than one partner in the last six months or who have a sexually transmitted disease
5. Sexually active men who have sex with men
6. Household contacts and sexual partners of persons who are chronically HBsAg-positive
7. Residents and staff of institutions for developmentally disabled persons
8. Staff of nonresidential child care and school programs for developmentally disabled persons if the program is attended by a known HBsAg-positive person
9. Patients undergoing hemodialysis

West Virginia Bureau for Public Health
Office of Epidemiology and Prevention Services
Division of Infectious Disease Epidemiology
350 Capitol Street, Room 125, Charleston, WV 25301-3715
Phone: 304.558.5358 Fax: 304.558.6335 www.dide.wv.gov

10. Patients with bleeding disorders who receive clotting factor concentrates
11. Members of households with adoptees who are HBsAg-positive
12. International travelers to areas in which HBV infection is of high or intermediate endemicity
13. Inmates of juvenile detention and other correctional facilities

Treatment

No specific therapy for *acute* HBV infection is available.
Patients should check with their doctor about treatment for chronic hepatitis B. The goal of treatment in patients with chronic HBV infection is to prevent progression to cirrhosis, hepatic failure, and hepatocellular carcinoma.

Surveillance Indicators

1. Proportion of acute cases with complete demographic information.
2. Proportion of acute cases with complete clinical information.
3. Proportion of acute cases with complete risk factor/exposure information.
4. Proportion of acute cases with complete vaccination history.
5. Proportion of acute cases that have received education and the date they were educated.
6. Proportion of acute cases reported to public health within the required timeframe.

West Virginia Bureau for Public Health
Office of Epidemiology and Prevention Services
Division of Infectious Disease Epidemiology
350 Capitol Street, Room 125, Charleston, WV 25301-3715
Phone: 304.558.5358 Fax: 304.558.6335 www.dide.wv.gov